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The Exemption from Patent Infringement and Declaratory Judgments: Misinterpretation of Legislative Intent?

The Drug Price Competition and Patent Term Restoration Act of 1984, partially codified as 35 U.S.C. section 271(e)(1), was enacted to encourage expenditure in the areas of pharmaceutical and medical inventions, and to ensure greater competition in these fields at an earlier date after relevant patents expire. However, the courts' interpretation of section 271(e)(1) may be preventing these original goals of Congress from being met. Recently, courts have based the denial of declaratory judgment actions upon section 271(e)(1). If interpreted as requiring the denial of all declaratory judgment suits, this statute may actually discourage companies from expending the money necessary to obtain FDA approval.

INTRODUCTION

The United States patent system serves the constitutional purpose of promoting the progress of science and the useful arts.¹ This purpose has historically been achieved through the careful balancing by Congress of the needs of society to have access to new inventions against the need to provide incentives to inventors by securing to them exclusive rights in their inventions.

The patent system creates incentive to invent by rewarding innovation, which in turn benefits society by providing new and useful products and improving technology.² Patent rights can be viewed as

1. U.S. CONST. art. I, § 8, cl. 8.

2. Former President Dwight D. Eisenhower stated:

Soundly based on the principle of protecting and rewarding inventors, this system has for years encouraged the imaginative to dream and to experiment — in garages and sheds, in great universities and corporate laboratories. From such explorations on the frontiers of knowledge has welled a flood of innovations and discoveries which have created new industries and reactivated old, giving more and more Americans better jobs and adding greatly to the prosperity and well-being of all.

1 ERNEST B. LIPSCOMB III, LIPSCOMB'S WALKER ON PATENTS § 1:9, at 58 (3d ed. 1984)

a contract between an inventor and society: "The inventor receives the right to control and profit from the first seventeen years of exploitation of this invention, and, in return," is obligated to disclose this invention to the public.³

"[D]isclosure of the invention gives the public the ability to develop or manufacture the product further after the patent term expires," and also allows other inventors to assess the scope of the patent.⁴ Thus, from its inception, the patent system has attempted to balance the incentive of a seventeen year monopoly⁵ with the interests of the public.⁶

This concept was articulated by the Supreme Court in *Graham v. John Deere Co.*:⁷

The patent monopoly was not designed to secure to the inventor his natural

(quoting Dwight D. Eisenhower).

3. Michael P. Chu, Note, *An Antitrust Solution to the New Wave of Predatory Patent Infringement Litigation*, 33 WM. & MARY L. REV. 1341, 1346 (1992). The author explains the contract theory of patent rights as follows:

In exchange for the inventor's disclosure of an invention previously unknown to the public, the government promises the inventor certain exclusive rights in the invention for a limited period of time. As a part of this contract, the inventor agrees to the government's publication of the invention upon expiration of the patent. During the time the patent contract is in force, the public has access to the published disclosure of the invention and can use its teachings in constructive thinking to forward the development of the art, whereby improvements are often promulgated. Members of the public may also approach the patent owner while the patent is in force seeking permission to practice the invention on terms suitable to the patent owner.

Id. at 1347 n.38 (quoting DAVID A. BURGE, PATENT AND TRADEMARK TACTICS AND PRACTICE 25 (2d ed. 1984)).

4. *Id.* at 1347. *See also* *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47 (1938). The *Schriber-Schroth* Court stated:

The object of the statute is to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent and "to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not."

Id. at 57 (quoting *Permutit Co. v. Graver Corp.*, 284 U.S. 52, 60 (1931)).

5. It has been argued that a patent is more a property right than a monopoly. *See* LIPSCOMB III, *supra* note 2, § 1:9, at 59. "The right of an inventor to his invention is no monopoly. It is no monopoly in any other sense than as a man's own house is a monopoly." *Id.* (quoting 1852 speech by Daniel Webster). *But see* *Graham v. John Deere Co.*, 383 U.S. 1, 9 n.2 (1966). The *Graham* Court stated:

If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself; but the moment it is divulged, it forces itself into the possession of every one . . .

Id. (quoting Letter from Thomas Jefferson to Isaac McPherson (Aug. 1813), in VI WRITINGS OF THOMAS JEFFERSON 180-81 (Washington ed. 1895)).

6. *See* *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944) ("It is the public interest which is dominant in the patent system."); *Vitamin Technologists, Inc. v. Wisconsin Alumni Research Found.*, 146 F.2d 941, 944 (9th Cir. 1944) ("It is now well established that a patentee may not put his property in the patent to a use contra to the public interest.").

7. 383 U.S. 1 (1966).

right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge. The grant of an exclusive right to an invention was the creation of society—at odds with the inherent free nature of disclosed ideas—and was not to be freely given. Only inventions and discoveries which furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly.⁸

Thus, there has existed throughout history a continuous tension between the public interest in benefiting from inventions and the private interests of patent owners in fully exploiting the exclusive rights afforded them.⁹

Congress balanced these competing interests by passing the Drug Price Competition and Patent Term Restoration Act of 1984, part of which is codified as 35 U.S.C. section 271(e)(1).¹⁰ The purpose of this Act was to create new incentives for expenditures for research and development and to make more low cost drugs available on the market. However, the courts' interpretation of section 271(e)(1) may be preventing these original goals of Congress from being met. In particular, the courts have recently used this section as a basis for denying declaratory judgment actions to both potential infringers and patent owners.¹¹ Such holdings could defeat the Act's goal of increasing research and development expenditures.

This Comment reviews the courts' treatment of the Drug Price Competition and Patent Term Restoration Act of 1984. Part I discusses the case history and legislative history of section 271(e)(1). Part II discusses the use of declaratory judgments in cases of alleged patent infringement, both when brought by the patentee and when brought by the alleged infringer. Part III provides an analysis of the recent cases involving declaratory judgment actions when the acts of one party fall under the protection of section 271(e)(1). Part IV concludes with a discussion of the potentially harmful effects of the

8. *Id.* at 9. The Court discussed the ambivalence of the Framers of the Constitution in allowing the patent monopoly. "[Thomas] Jefferson, like other Americans, had an instinctive aversion to monopolies. It was a monopoly on tea that sparked the Revolution and Jefferson certainly did not favor an equivalent form of monopoly under the new government." *Id.* at 7.

9. See generally A. Samuel Oddi, *Beyond Obviousness: Invention Protection in the Twenty-First Century*, 38 AM. U. L. REV. 1097, 1097-106 (1989) (discussing the role of the patent system in society).

10. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, 282 (1984)), reprinted in 1984 U.S.C.C.A.N. 2647.

11. See *Farmaceutisk Laboratorium Ferring v. Solvay Pharmaceuticals, Inc.*, 25 U.S.P.Q.2d (BNA) 1344 (N.D. Ga. 1992); *Intermedics, Inc. v. Ventritex Co.*, 26 U.S.P.Q.2d (BNA) 1524 (Fed. Cir. 1993); *Teletronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992).

courts' interpretation of section 271(e)(1).

I. THE EXEMPTION TO INFRINGEMENT UNDER SECTION 271(e)(1)

A. *History of the Drug Price Competition Patent Term Restoration Act of 1984*

The Drug Price Competition and Patent Term Restoration Act of 1984 (PTR Act)¹² consists of two main titles: Title I addresses "Abbreviated New Drug Applications,"¹³ and Title II covers "Patent Term Restoration."¹⁴ The PTR Act was enacted to serve two objectives: (1) to make more low cost generic drugs available to the public and (2) to create new incentives for research and development of certain products subject to premarket approval by the government.¹⁵ In enacting Title II of the PTR Act, Congress attempted to accomplish these objectives by correcting two unintended distortions of the seventeen year patent monopoly as it applies to certain products that require government approval prior to marketing. The first unintended distortion is a shortening of the useful life of the patent for a new, "pioneer" drug or medical device. Because a patent is generally obtained as soon as a potentially useful product is discovered, part of the life of the patent is wasted during the time required to obtain FDA approval of the new product prior to marketing. The second distortion occurs at the other end of the patent term. Because use of a patented product for the submission of data to the FDA was considered infringement,¹⁶ a party wishing to compete with the patentee could not begin the process of obtaining FDA approval until after the expiration of the patent. Thus, the patentee's *de facto* monopoly would continue for an often substantial period of time until FDA approval of competing products could be obtained.¹⁷

The PTR Act was the result of a compromise between two competing economic groups: the generic drug industry and the pioneer drug industry. These groups each lobbied Congress for the passage of legislation to eliminate the patent distortion most harmful to their

12. Drug Price Competition and Patent Term Restoration Act of 1984, *supra* note 10.

13. Title I was codified as 21 U.S.C. § 355 (1984). The Abbreviated New Drug Applications (ANDA) provision establishes a new generic drug approval procedure which increases the rate at which generic drugs are approved by the FDA.

14. Title II was codified as 35 U.S.C. §§ 156, 271 (1984).

15. H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. 1, at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

16. *Roche Prods., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984).

17. H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. 1, at 46 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2679; *see also* *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 670 (1990).

respective industries.¹⁸ After lengthy negotiations, these groups arrived at a compromise which they presented to key members of the Senate and House.¹⁹ This compromise was eventually enacted as the PTR Act.

The PTR Act eliminated the first patent term distortion, the shortening of the effective term of a patent, by providing for the extension of the seventeen year patent term for the earliest of certain products subject to pre-market approval.²⁰ The PTR Act added a new section to the U.S. Patent Code, which allowed for patent term extensions of "drug product[s], medical devices, food additive[s], [and] color additive[s] subject to regulation under the Federal Food, Drug, and Cosmetic Act."²¹ The pioneer drug industry pressed for the approval of this bill, which provides incentives for expenditure in research and development by restoring to the inventor some of the time lost on patent life while the product is awaiting pre-marketing approval.²²

At the urging of the generic drug industry,²³ Congress also attempted to eliminate the second distortion of the patent term, the *de facto* monopoly of the pioneer drug patent while competitors sought FDA approval. This was accomplished by amending the Patent Code to include section 271(e)(1), which provides that "[i]t shall not be an act of [patent] infringement to make, use, or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates

18. H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. 1, at 17-18 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2650-51. The representatives of the pioneer pharmaceutical industry testified before several congressional committees that the average effective patent term of drugs had declined due to government review of new drugs. These representatives argued that this decline would result in decreased expenditures for the research and development of new drugs, and argued for patent term extensions to correct this loss in patent term. *Id.* See also H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. 2, at 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688 (explaining that FDA rules on generic drug approval have serious anti-competitive effects).

19. See Alan D. Lourie, *Patent Term Restoration*, 66 J. PAT. OFF. SOC'Y 526 (1984) (describing the negotiations between the generic and pioneer drug industries which resulted in the PTR Act).

20. H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. 1, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

21. 35 U.S.C. § 156(f)(1) (1988).

22. H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. 2, at 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688. The pioneer drug industry was represented primarily by the Pharmaceutical Manufacturers Association.

23. *Id.* The generic drug industry was primarily represented by the Generic Pharmaceutical Industry Association.

the manufacture, use, or sale of drugs.”²⁴ Prior to section 271(e)(1), gathering data for FDA approval before the expiration of a relevant patent constituted patent infringement under section 271(a).²⁵

The generic drug industry pressed for the passage of section 271(e)(1) to overrule previous court decisions which effectively extended a patentee’s monopoly and frustrated the provision of generic drug substitutes to the public.²⁶ These court decisions, holding that activity before the FDA constituted infringement, were *Pfizer, Inc. v. International Rectifier Corp.*²⁷ and *Roche Products, Inc. v. Bolar Pharmaceutical Co.*²⁸ These decisions were based upon interpretation of the common law infringement exception for experimental use.²⁹ In *Pfizer*, the court held that for activity to be classified under the common law exemption for experimental use, the activity must not be related to any commercial use.³⁰

Roche was decided on similar grounds, and followed the rule in *Pfizer*. In *Roche*, the defendant generic drug company had engaged in obtaining FDA approval of the generic form of Roche’s patented drug prior to the expiration of that patent.³¹ The court held that such use constituted infringement, because it was solely for business purposes. Thus, the use did not fall within the common law experimental use exemption,³² which allowed for the use of patented products in certain situations without constituting infringement.³³

24. 35 U.S.C. § 271(e)(1) (1988).

25. *Id.* § 271(a) (“Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.”).

26. Susan E. Kopp, *The Drug Price Competition and Patent Term Restoration Act of 1984: Is it a Healthy Long Term Solution?*, 71 J. PAT. OFF. SOC’Y 945, 953 (1989) (discussing generic industry’s reasons for opposing the decision in *Roche Prods., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984)).

27. 217 U.S.P.Q. (BNA) 157 (C.D. Cal. 1982).

28. 733 F.2d 858 (Fed. Cir. 1984).

29. The experimental use defense was first introduced by Justice Story in *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600), stating, in dictum, that “it could never have been the intention of the legislature to punish a man, who constructed such a [patented] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.” *Id.* at 1121.

30. *Pfizer*, 217 U.S.P.Q. (BNA) at 161 (holding that use of patented drug by generic drug manufacturer in performing clinical tests of drug prior to expiration of patent constituted infringement).

31. *Roche*, 733 F.2d at 860.

32. *Id.* at 863. The court stated:

Bolar’s intended “experimental” use is solely for business reasons and not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry. . . . Bolar may intend to perform “experiments,” but unlicensed experiments conducted with a view to the adaption of the patented invention to the experimenter’s business is a violation of the rights of the patentee to exclude others from using his patented invention.

Id.

33. Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights*

Through the PTR Act, Congress passed section 271(e)(1) to overrule *Bolar* specifically.³⁴ The reason for this Congressional overruling is explained in the history of the PTR Act as follows: "Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. That limited time should be a definite time and, thereafter, immediate competition should be encouraged."³⁵

Section 271(e)(1) was not met with complete approval. Several members of Congress were concerned that section 271(e)(1) would drastically alter patent law. For instance, Congressman Moorhead stated that

[e]nactment of this section would create an unprecedented exception to the exclusionary rights to which a patent holder is entitled during the patent term. Overturning the *Bolar* decision would allow experimental use of a drug product prior to the expiration of the patent. There is no legitimate basis for distinguishing between the exclusionary rights accorded a pharmaceutical manufacturer during the patent term and those enjoyed by any other patent holder. . . .

For this reason, section 202 should be amended to permit experimental use of a drug by a non-patentee only during the period for which the patent has been extended.³⁶

In spite of such controversy, the Patent Code was amended to include section 271(e)(1).

B. Application of The Patent Term Restoration Act

The PTR Act was the result of a narrow compromise between the generic and pioneer pharmaceutical industries.³⁷ However, since the passing of section 271(e)(1), contained in section 202 of the PTR Act, the courts have progressively expanded this element of the "compromise" beyond anything contemplated by either the generic

and *Experimental Use*, 56 U. CHI. L. REV. 1017 (1989) (discussing the experimental use exception and arguing that even this narrow exception to infringement might be too broad).

34. H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. 1, at 45-46 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2678-79. The Act sought to overrule the decision in *Roche*, because "[i]t is the Committee's view that experimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent, but prevention of such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date." *Id.*

35. *Id.* at 46, *reprinted in* 1984 U.S.C.C.A.N. at 2679.

36. 130 CONG. REC. 24,456-57 (1984).

37. Lourie, *supra* note 19, at 544 (explaining that while the bill was not entirely satisfactory to either the generic or pioneer pharmaceutical industries, both groups testified to Congress that they supported the bill and considered it to be the best compromise obtainable).

and pioneer pharmaceutical industries or by Congress.

The first expansion of section 271(e)(1) occurred in the Supreme Court decision *Eli Lilly & Co. v. Medtronic Inc.*,³⁸ in which the Court held that section 271(e)(1) applies to medical devices as well as to drugs. In this case, Eli Lilly owned a patent on an implantable cardiac defibrillator, a medical device used in the treatment of heart patients. Eli Lilly brought an infringement action against another manufacturer, Medtronic, alleging that Medtronic's testing of the defibrillator infringed upon Lilly's patent.³⁹ Medtronic defended on the ground that its activities were undertaken to develop and submit to the FDA the information necessary to obtain marketing approval for the device, and thus were exempt from a claim of infringement under section 271(e)(1).⁴⁰ In deciding the case in favor of Medtronic, the Supreme Court reasoned that although the statute is ambiguous, it is more naturally construed to include any patented invention that is regulated by the FDA.⁴¹ The Court reasoned that since the purpose of the PTR Act was to remedy the distortions at both ends of the patent term, section 271(e)(1) should apply to any product eligible for patent term extension under section 156.⁴² Thus, even though section 271(e)(1) fails to expressly include products other than drugs, the Court's ruling effectively expanded section 271(e)(1) to include any product which is regulated by the FDA.

While there are policy arguments both for and against this expansion of section 271(e)(1) to medical devices,⁴³ the end result is an expansion of section 271(e)(1) beyond that which was considered by

38. 496 U.S. 661 (1990).

39. *Id.* at 664.

40. *Id.*

41. *Id.* at 665. The Court stated that the statutory phrase of section 271(e)(1), "a Federal law which regulates the manufacture, use, or sale of drugs," is ambiguous. *Id.* (quoting 35 U.S.C. § 271(e)(1) (1982)).

It is somewhat more naturally read (as Medtronic asserted) to refer to the entirety of any Act, including the FDCA [Federal Food, Drug, and Cosmetic Act] at least some of whose provisions regulate drugs, rather than (as Eli Lilly contended) to only those individual provisions of federal law that regulate drugs. However, the text, by itself, is imprecise and not plainly comprehensible on either view.

42. *Id.* at 672. The Court stated:

It seems most implausible to us that Congress, being demonstrably aware of the dual distorting effects of the regulatory approval requirements . . . should choose to address both those distortions only for drug products; and for other products named in . . . [section 156] should enact provisions which not only leave in place an anticompetitive restriction at the end of the monopoly term but simultaneously expand the monopoly term itself, thereby not only failing to eliminate but positively aggravating the distortion of the 17-year patent protection.

Id. at 672-73.

43. Todd A. Rathe, *Medical Device Experimental Use Exception in Patent Infringement: Eli Lilly v. Medtronic*, 16 J. CORP. L. 625, 639-42 (1991) (discussing policies supporting and opposing the Court's decision).

Congress in the passing of the PTR Act.⁴⁴

A second and potentially more harmful expansion of section 271(e)(1) is the denial of declaratory judgment actions when one party is gathering data for the FDA approval of a product which the party intends to market prior to the expiration of the relevant patent. In several recent cases, section 271(e)(1) has been used to deny declaratory judgment actions to both potential infringers and patent owners.⁴⁵

A review of the use of declaratory judgments in patent cases is given below in Part II to explain the importance of these actions in the patent system.

II. DECLARATORY JUDGMENT ACTIONS IN PATENT LAW

Declaratory judgment actions are useful procedures for establishing the respective rights of patent owners and potential infringers.⁴⁶ When used by patent owners in infringement litigation, declaratory judgment actions expand intellectual property protection by providing an additional procedural remedy.⁴⁷ In the hands of potential infringers, declaratory judgment actions can be used to prevent patent owners from abusing the power of their patents by inhibiting competition.⁴⁸ These actions help assure that society receives adequate benefit for the granting of the patent monopoly.

44. Ellen J. Flannery & Peter B. Hutt, *Balancing Competition and Patent Protection in the Drug Industry: The Drug Price Competition and Patent Term Restoration Act of 1984*, 40 FOOD DRUG COSM. L.J. 269 (1985). "Because section 271(e) was intended solely to overrule . . . [Roche], it is narrow in application. This statutory provision applies only to a patented human drug product, not to any other invention." *Id.* at 308.

45. See *Farmaceutisk Laboratorium Ferring v. Solvay Pharmaceuticals, Inc.*, 25 U.S.P.Q.2d (BNA) 1344 (N.D. Ga. 1992); *Intermedics, Inc. v. Ventritex Co.*, 26 U.S.P.Q.2d (BNA) 1524 (Fed. Cir. 1993); *Teletronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520 (Fed. Cir. 1992).

46. See 6A JAMES W. MOORE, *MOORE'S FEDERAL PRACTICE* § 57.20 (2d ed. 1982).

47. See 10A CHARLES A. WRIGHT ET AL., *FEDERAL PRACTICE AND PROCEDURE* § 2751 (2d ed. 1983) (stating that availability of declaratory judgment remedy expands judicial discretion).

48. *Societe de Conditionnement en Aluminium v. Hunter Eng'g Co.*, 655 F.2d 938, 943 (9th Cir. 1981). "The availability of declaratory relief serves both judicial efficiency and the policies underlying the patent laws. Before passage of the Act, a patentee had more protection for his invention than his statutory monopoly warranted." *Id.*

A. Use of Declaratory Judgments by Potential Infringers

From the perspective of a party threatened with potential liability, a declaratory judgment provides a means by which to avoid waiting until the opposing party decides to bring a suit, possibly at a time after the damage has occurred.⁴⁹ Declaratory judgment thus minimizes the danger of avoidable loss and the unnecessary accrual of damages. For the potential infringer, declaratory judgment permits the settlement of controversies before his actions develop into actual violations of law.⁵⁰ The availability of declaratory judgment actions prevents a patent owner from suppressing the competition with threats of infringement suits without actually having to subject its patent to the test of litigation.⁵¹ The effect of declaratory judgment actions may be explained as follows:

[I]t may be noted that the availability of declaratory relief has destroyed the "racket" by which patentees gained manifold advantage by the device of threatening alleged infringers or their customers with lawsuits which might never be brought or, if brought, could always be dismissed without prejudice, without the possibility of such persons taking steps to ascertain the validity of the patentee's claims.⁵²

Declaratory relief can thus afford parties a practical, expedient, and inexpensive means for determining their respective rights in a single proceeding.⁵³ Such an expedient means is very desirable in intellectual property disputes, where enormous financial liabilities are at stake and substantial damages are awarded when a patent is infringed.⁵⁴

B. Use of Declaratory Judgments by Patent Owners

While declaratory relief has traditionally been available to potential infringers, a more recent development in patent law is the availability of declaratory judgment actions to patent owners. Such suits allow a patent owner to prevent injury to its market position by testing whether a potentially infringing product will actually infringe

49. See *E. Edlmann & Co. v. Triple-A Specialty Co.*, 88 F.2d 852, 854 (7th Cir. 1937), *cert. denied*, 300 U.S. 680 (1937) (noting that in promulgating the Declaratory Judgment Act, Congress intended "to avoid accrual of avoidable damages to one not certain of his rights and to afford him early adjudication without waiting until his adversary should see fit to begin suit.").

50. *Maryland Casualty Co. v. Rosen*, 445 F.2d 1012, 1014 (2d Cir. 1971).

51. See *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.* 846 F.2d 731, 734-35 (Fed. Cir. 1988) (explaining the benefits of the availability of declaratory relief to potential infringers).

52. *Wembley, Inc. v. Superba Cravats, Inc.*, 315 F.2d 87, 89 (2d Cir. 1963).

53. See *Smith v. Transit Casualty Co.*, 281 F. Supp. 661, 670 (E.D. Tex. 1968) (stating that declaratory judgment is less costly than protracted litigation).

54. 35 U.S.C. § 284 (1988) (explaining that a patentee may recover up to three times the damages found by a court for patent infringement).

before it is introduced into the marketplace. Although the use of declaratory judgment by a patent owner against a potential infringer was first allowed in 1963,⁵⁵ the acceptance of such suits has been slow, and a significant number of decisions have taken the position that such suits are not proper under any circumstances.⁵⁶

An important case in establishing the availability of declaratory relief for patent owners was *Lang v. Pacific Marine and Supply Co.*⁵⁷ In this case the court held that declaratory relief should be available to patentees in situations where a potential infringer could maintain a similar action.⁵⁸ As the court in *Lang* stated: "We see no reason why a patentee should be unable to seek a declaration of infringement against a future infringer when a future infringer is able to maintain a declaratory judgment action for noninfringement under the same circumstances."⁵⁹ Thus, the duality of declaratory judgment was established. The resolution of disputes by declaratory judgment, whether brought by the potential infringer or patentee, clearly fulfills the legislative intent of the Declaratory Judgment Act.⁶⁰

55. *Proler Steel Corp. v. Luria Bros. & Co.*, 223 F. Supp. 87 (S.D. Tex. 1963) (holding that patent owners may employ declaratory actions against potential infringers).

56. See *Swedlow, Inc. v. Rohm & Haas Co.*, 455 F.2d 884, 886-87 (9th Cir. 1972) (arguing that conventional use of declaratory judgment precludes use by patent owners who have a corollary remedy available in patent infringement suit); see also 1 DONALD S. CHISUM, PATENTS § 21.02[1], at 21-89 to 21-90 (1994). Chisum explains the concerns of courts causing them to rule against such suits:

First is [the] concern that [the] defendant may not actually go forth with its threatened acts or may so alter them as to change the issues substantially. Thus to rule on a declaratory judgment would be to render an advisory opinion Second is the concern that the patent owner, unlike an infringer, already has an express statutory remedy. . . . Third is [the] concern that entertaining such suits will subvert the restrictive venue provision in 28 U.S.C. § 1400(b).

Id.

57. 895 F.2d 761 (Fed. Cir. 1990).

58. *Id.* at 764.

59. *Id.*

60. *Altwater v. Freeman*, 319 U.S. 359, 365 (1943) (citing S. REP. NO. 1005, 73d Cong., 2d Sess. 2-3 (1934)) (stating that the purpose of the Declaratory Judgment Act is to afford relief against "peril and insecurity" of potential damages in infringement suits); see also *Wembly Inc. v. Superba Cravats, Inc.*, 315 F.2d 87, 90 (2d Cir. 1963) (arguing that the rationale for allowing declaratory judgment is avoidance of economic waste incurred in embarking on a program of manufacture, use, or sale that turns out to be illegal).

C. Operation of the Declaratory Judgment Act: The Need for an Actual Controversy

Jurisdiction under the Declaratory Judgment Act is not dependent on the actual commission of an infringing act. Because the purpose of the Declaratory Judgment Act is to allow a party to ascertain his or her rights before damages accrue and economic waste is incurred, this purpose would be thwarted if a judicial determination of rights could not be secured prior to any act of infringement.⁶¹ For a court to grant declaratory relief, the declaratory judgment action must contain a "true and actual controversy."⁶²

The Supreme Court developed a general two-prong test to assist courts in determining if a controversy exists.⁶³ Courts have applied this test to cases both where the plaintiff is the potential infringer and where the plaintiff is the patentee. For a holding of justiciability under the Declaratory Judgment Act when the plaintiff is the potential infringer, the two elements of the test are: (1) The defendant's conduct must have created on the part of the plaintiff a reasonable apprehension of a charge of infringement by the defendant, and (2) the plaintiff must be engaging in the infringing acts or have the ability and intention to immediately engage in such acts.⁶⁴

For such a holding when the plaintiff is the patentee, the defendant must be engaged in an activity subject to an infringement charge under section 271(a),⁶⁵ or be in the meaningful preparation for such an activity. In addition, "acts of the defendant must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming."⁶⁶

In declaratory judgment actions brought by potential infringers, the first criterion of the test for actual controversy — requiring a reasonable apprehension of a suit for infringement — has been liberally construed by the courts, and an express charge of infringement by the defendant is not required.⁶⁷ The conduct of the patent owner

61. Jerry D. Voight, *Declaratory Judgment Actions in Patent Cases Where There Has Been No Act of Infringement*, 72 J. PAT. OFF. SOC'Y 1136, 1141 (1990) (reviewing case law in which declaratory judgments have been sought by either alleged infringers or patent owners to resolve disputes prior to commission of any act that would constitute patent infringement).

62. 28 U.S.C. § 2201 (1988 & Supp. V 1993) ("In a case of actual controversy . . ."); see also *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed. Cir. 1988).

63. *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed. Cir. 1987).

64. *Arrowhead*, 846 F.2d at 736.

65. 35 U.S.C. § 271(a) (1988) (defining infringement as the making, using, or selling of a patented product).

66. *Lang v. Pacific Marine & Supply Co.*, 895 F.2d 761, 764 (Fed. Cir. 1990).

67. *Arrowhead*, 846 F.2d at 736 (stating that "[i]n light of the subtleties in lawyer

must be examined to determine the reasonableness of the apprehension of an infringement suit.⁶⁸ Reasonable apprehension can be created through various means short of an actual charge of infringement, including letters sent to a competitor or his customers by the patent owner,⁶⁹ or a history of litigation by the patent owner to enforce patent rights.⁷⁰ Although the reasonable apprehension criterion of the test is more liberally construed for plaintiffs who are potential infringers than for plaintiffs who are patent owners, the court in *Lang* also made this prong of the test somewhat easier for patent owners, stating that "[a] concern that the alleged future infringer might alter its course of conduct . . . should not cause a dismissal any more than it should in a suit by the accused infringer."⁷¹

The most difficult aspect for either patent owners or potential infringers in suits brought prior to an actual act of infringement is establishing the immediacy of the future infringer's ability to make, sell, or use a patented product.⁷² For a determination of justiciability, "[m]ajor stress should be placed on the 'definite' intention of the plaintiff to take 'immediate' action to utilize its potential and this intention should be 'evident' from the preparatory steps outlined in its complaint."⁷³ A party must be able and ready and have the intent, capacity, and power to perform the potentially infringing act.⁷⁴

language, however, the courts have not required an express infringement charge").

68. *Id.* The *Arrowhead* court stated:

If the circumstances warrant, a reasonable apprehension may be found in the absence of *any* communication from defendant to plaintiff If, on the other hand, defendant has done nothing but obtain a patent, there can be no basis for the required apprehension, a rule that protects quiescent patent owners against unwarranted litigation.

Id. (emphasis added) (citation omitted).

69. *Sticker Indus. Supply Corp. v. Blaw-Knox Co.*, 367 F.2d 744 (7th Cir. 1966).

70. *Sweetheart Plastics, Inc. v. Illinois Tool Works, Inc.*, 439 F.2d 871, 874 (1st Cir. 1971).

71. *Lang v. Pacific Marine & Supply Co.*, 895 F.2d 761, 764 (Fed. Cir. 1990).

72. *General Tire & Rubber Co. v. Jefferson Chem. Co.*, 46 F.R.D. 607, 610 (S.D.N.Y. 1969) (explaining that although the requirements for declaratory judgment had relaxed to allow actions to proceed before any act of infringement had occurred, there was still a need for "presenting proof of the concurrence of some form of present or potential infringement").

73. *Wembly, Inc. v. Superba Cravats, Inc.*, 315 F.2d 87, 90 (2d Cir. 1963).

74. *Zenith Lab. Inc. v. Bristol-Myers Squibb Co.*, 24 U.S.P.Q.2d (BNA) 1641, 1645 (D.N.J. 1991) (opinion not for publication).

D. Declaratory Judgments and the Contingency of FDA Approval

The existence of conditions precedent to, or contingencies upon the ability of a party to market a product have caused courts to find that no actual controversy exists. Consequently, it has often been difficult to establish an actual controversy when the potentially infringing party is seeking the approval of the FDA for its product.⁷⁵ However, since a controversy sufficient to support a declaratory judgment action for threatened infringement is not precluded because of the absence of current infringement,⁷⁶ the contingency of FDA approval is not always fatal to the finding of justiciability. First, courts look to a potential infringer's level of preparation and present expenditures on the manufacture of the product to determine the existence of an actual controversy. Courts place emphasis upon the certainty or definiteness that the alleged infringing activity would occur, rather than on the immediacy of the occurrence.⁷⁷ The level of preparation can be used to show the intent and capacity of a party to market an infringing product. As the Federal Circuit Court of Appeals stated in *Arrowhead Industrial Water, Inc. v. Ecolochem, Inc.*, "[w]hether a declaratory plaintiff's ability and definite intention to undertake a potentially infringing activity constitutes sufficient 'preparation' is a question of degree to be resolved on a case-by-case basis."⁷⁸ Thus, even when marketing is contingent upon FDA approval, courts may find that sufficient preparation has occurred to support the finding of an actual controversy.

Second, courts have also found that activities related to the seeking of FDA approval can suffice to show the existence of an actual controversy. For example, in *Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co.*,⁷⁹ the plaintiff was a potential infringer that

75. *Id.* at 1646 (stating that "[w]here certain barriers exist to marketing of product, and it is uncertain that market conditions would be favorable at time barriers are removed 'there is simply not a sufficient degree of immediacy to warrant the issuance of a declaratory judgment'" (citations omitted)).

76. See *Automation Sys., Inc. v. Intel Corp.*, 501 F. Supp. 345, 347 (S.D. Iowa 1980) ("It will be to no one's advantage to wait for a consideration of the infringing character of a product or process until the actual infringement takes place since this only serves to increase the resulting potential economic harm."); see also *Kasper v. Cooper Canada Ltd.*, 688 F. Supp. 347, 352 (N.D. Ill. 1988) (stating that a requirement that there be actual infringement before a declaratory judgment action could proceed would completely defeat the purpose of declaratory relief).

77. *Ethicon, Inc. v. American Cyanamid Co.*, 369 F. Supp. 934 (D.N.J. 1973) (finding that an actual controversy existed even though the marketing of the potentially infringing product was contingent upon FDA approval, which might take a considerable amount of time).

78. *Arrowhead Water Indus., Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988).

79. *Zenith Lab., Inc. v. Bristol-Myers Squibb Co.*, 24 U.S.P.Q.2d (BNA) 1641 (D.N.J. 1991).

sought to market its product upon FDA approval, prior to the expiration of the relevant patent. The court held that the "use" of a patented product in connection with submissions to the FDA constituted infringement, and thus established the existence of an actual controversy.⁸⁰

The court in *Zenith* also addressed the discretionary nature of the Declaratory Judgment Act. Even when actual controversies exist, courts are given discretion in declaratory actions in order to "enable the court to make a reasoned judgment whether the investment of judicial time and resources in a declaratory action will prove worthwhile in resolving a justiciable dispute."⁸¹ The important elements in a court's use of its discretion to allow declaratory relief are (1) whether a delay in an adjudication of rights will result in harm that would be avoided by an immediate declaration of those rights, and (2) whether a useful purpose would be achieved by deciding a party's rights.⁸²

The court in *Zenith* found that two "useful purposes" would be achieved by a declaration of Zenith's rights. First, the declaration would allow Zenith to make an informed decision whether to continue prosecution of its application before the FDA, to abandon the application, or to amend it to reflect Zenith's intent to wait until the expiration of the Bristol-Myers patent to market its product.⁸³ Second, the court found that a declaration of Zenith's rights, if Zenith's product did not infringe, would avoid any delay in the marketing of this product. This would result in a lower cost drug becoming available to the public more quickly.⁸⁴

The court's decision in *Zenith* is consistent with the purpose of the Declaratory Judgment Act and with the purpose of the U.S. Patent system. The decision provides for an early adjudication of rights, which saves money and allows for the earlier marketing of products

80. *Id.* at 1647.

81. *Minnesota Mining & Mfg. Co. v. Norton Co.*, 929 F.2d 670, 672 (Fed. Cir. 1991).

82. *Id.* at 673; *Zenith Lab.*, 24 U.S.P.Q.2d (BNA) at 1647. The *Zenith* court stated: "The decision to exercise declaratory judgment jurisdiction requires a balancing of competing considerations. The Court's interest in 'conserving limited judicial resources' must be balanced against the interest of 'a party threatened with legal action in obtaining an early adjudication of its rights and liabilities.'" *Id.*

83. *Zenith Lab.*, 24 U.S.P.Q.2d (BNA) at 1647.

84. *Id.* The court stated: "If in fact [Zenith's product] does not infringe Bristol's rights, the public is entitled as soon as possible to the benefit of that product, most likely at a cost lower than is currently available from Bristol or its licensees." *Id.*

which benefit the public. However, some courts have reached decisions contrary to the holding in *Zenith* and have denied declaratory relief in cases where one party is seeking FDA approval. In particular, the use of the exemption to infringement under section 271(e)(1) has caused courts to deny declaratory relief to parties in situations similar to *Zenith*.

IV. SECTION 271(e)(1) AS A BASIS FOR DENIAL OF DECLARATORY JUDGMENTS

In two recent decisions, *Intermedics, Inc. v. Ventritex Co.*⁸⁵ and *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*,⁸⁶ the Federal Circuit Court of Appeals denied patentees' declaratory judgment actions because they did not present a "sufficient case of controversy"⁸⁷ on which it could make a decision.⁸⁸ The court based its rulings on the fact that the defendant's acts, which would normally constitute infringement under 271(a) of the Patent Act,⁸⁹ were protected by an exception found in section 271(e)(1) of the same act. This ruling eliminated the ability of the patent owners to prevent any injury to their market position caused by the defendant's introduction of an infringing product to the marketplace. If section 271(e)(1) had not been applied, under the rule of *Roche*, the acts of the defendants could have been found to constitute infringement.⁹⁰

One commentator correctly observed that section 271(e)(1) was intended to "reverse *Roche*, only to the extent that a company had no intent to commercialize the invention before the patent expiration date."⁹¹ This position is supported by language in the PTR Act, which explains the purpose of the Act as follows: "Finally, Title II provides that it is not an act of patent infringement for a generic drug maker to import or to test a patented drug in preparation for seeking FDA approval *if marketing of the drug would occur after the expiration of the patent.*"⁹² This interpretation of section

85. 26 U.S.P.Q.2d (BNA) 1524 (Fed. Cir. 1993). The *Intermedics* court upheld the district court's ruling that Ventritex's allegedly infringing uses of its implantable defibrillator fell within the patent infringement clinical trial exemption of 35 U.S.C. § 271(e)(1) and that the application of this exemption precluded granting declaratory relief to Intermedics. *Id.*

86. 982 F.2d 1520 (Fed. Cir. 1992).

87. Declaratory Judgment Act, 28 U.S.C. § 2201 (1988 & Supp. V 1993). For a general discussion see *supra* notes 61-74 and accompanying text.

88. *Intermedics*, 26 U.S.P.Q.2d (BNA) at 1528; *Telectronics*, 982 F.2d at 1526.

89. 35 U.S.C. § 271(a) (1988), which states: "Except as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." *Id.*

90. See *supra* notes 31-33 and accompanying text.

91. Lourie, *supra* note 19, at 541.

92. H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. 1, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648 (emphasis added).

271(e)(1) would be most consistent with the dual intent of the PTR Act: making low cost generic drugs available to the public, and creating new incentives for research and development of products subject to FDA approval.

Unfortunately, courts do not appear to be using this interpretation. In *Intermedics, Inc. v. Ventritex Co.*,⁹³ the Court of Appeals for the Federal Circuit affirmed the decision of the district court,⁹⁴ which had denied declaratory relief to the plaintiff. The plaintiff, Intermedics, had reason to believe that Ventritex would begin the marketing of their potentially infringing product prior to the expiration of Intermedics' patents.⁹⁵ Ventritex had developed an implantable defibrillator, named "Cadence," which Intermedics claimed infringed seven of its patents relating to implantable defibrillators.⁹⁶ Intermedics identified several activities by Ventritex which Intermedics believed constituted infringement under section 271(a). These activities included manufacturing several hundred Cadences, selling the Cadence to hospitals in the U.S. and to international distributors, testing the Cadence, and demonstrating the Cadence at medical trade shows.⁹⁷ Ventritex admitted that it intended to market the Cadence as soon as it secured FDA approval, even if this was before the expiration of Intermedics' patents.⁹⁸ However, Ventritex argued that because its uses of the Cadence were all related to the seeking of FDA approval,⁹⁹ it was entitled to the exemption under section 271(e)(1).¹⁰⁰ Intermedics argued that the exemption under section 271(e)(1) for the making, using, and selling activities should not apply upon a showing that Ventritex intended to commercialize their allegedly infringing product before Intermedics' patent expired. The court denied declaratory relief, stating that there was no suggestion in the language of section 271(e)(1) that a producer may not use the exemption if it intends to commercialize the product before the expiration of the relevant patents.¹⁰¹ The court went on to state

93. 26 U.S.P.Q.2d (BNA) 1524 (Fed. Cir. 1993).

94. *Intermedics, Inc. v. Ventritex Co.*, 775 F. Supp. 1269, 1272 (N.D. Cal. 1991).

95. *Intermedics*, 26 U.S.P.Q.2d (BNA) at 1524.

96. *Intermedics*, 775 F. Supp. at 1272.

97. *Id.* at 1280.

98. *Id.* at 1275.

99. *Id.* at 1281-85.

100. *Intermedics*, 26 U.S.P.Q.2d (BNA) at 1525.

101. *Id.* The court explained that "[i]f the statutory language is clear, the plain meaning of the statute controls. The plain language of section 271(e)(1) does not contain the limitation that Intermedics desires to find therein." *Id.* at 1528 (citations omitted).

that even if the statutory language of section 271(e)(1) were not clear, the legislative history of the PTR Act of 1984 does not support the position proposed by Intermedics.¹⁰² The court based this finding upon the fact that “Congress specifically rejected an amendment to the Act that would have permitted testing only during the last year of any patent term.”¹⁰³

However, the court’s reliance on the legislative history was flawed. In stating its reasons for rejecting that proposed amendment, Congress made it clear that the rejection was based on the fact that Congressman Moorhead’s proposed amendment would not eliminate the extension of a patentee’s *de facto* monopoly. Congress explained their reasoning as follows:

The Committee rejected the Moorhead amendment for two reasons. First, the only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute. The patent holder retains the right to exclude others from the major commercial marketplace during the life of the patent. . . . Second, . . . the Committee reasoned that without section 202 generic manufacturers would be required to engage in these bioequivalency tests after the expiration of the patent. This would result in delays of about two years after the expiration of the patent before a generic could go on the market.¹⁰⁴

This discussion makes it clear that the reason for the rejection of Congressman Moorhead’s amendment was not that Congress intended section 271(e)(1) to provide shelter for all products seeking FDA approval, regardless of when these products are to be commercialized. Rather, the amendment was rejected because, by only allowing FDA activity of a generic substitute in the last year of a patent, the amendment hindered the goal of getting generic substitutes on the market as soon as possible *after the expiration of the relevant patents*.

In addition, in both *Intermedics* and in a similar case, *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*,¹⁰⁵ the Federal Circuit reached its decision that section 271(e)(1) applied by broadly interpreting the statutory language “solely for uses reasonably related to” obtaining FDA approval.¹⁰⁶ The court chose to focus upon the words “reasonably related to” and all but ignored the word “solely.” In both cases, the defendant in the declaratory judgment action had

102. *Id.* at 1528. The court stated that “the legislative history of section 271(e)(1) does not support the reading Intermedics proposes, even though Congress was clearly aware of the economic repercussions of the section 271(e)(1) exemption.” *Id.*

103. *Id.* (referring to the amendment proposed by Mr. Moorhead, discussed *supra* note 36 and accompanying text).

104. H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. 2, at 8 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2692.

105. 982 F.2d 1520 (Fed. Cir. 1992).

106. 35 U.S.C. § 271(e)(1) (1988).

demonstrated their potentially infringing product at medical conferences, disseminated data obtained from clinical trials to physicians and investors, and otherwise used their data and product to create a ready market once FDA approval was granted.¹⁰⁷ While such uses would not constitute infringement under section 271(a), they clearly are not "solely" related to the obtaining of FDA approval, and thus section 271(e)(1) should not apply. Courts have held that a court "should avoid an interpretation of a statute that renders any part of it superfluous and does not give effect to all of the words used by Congress."¹⁰⁸ Eliminating the word "solely" from section 271(e)(1) would clearly be contrary to Congress' intent to enact a narrow compromise between pioneer and generic drug companies.

Another case, *Farmaceutisk Laboratorium Ferring v. Solvay Pharmaceuticals, Inc.*,¹⁰⁹ illustrates that section 271(e)(1) is also being used to deny declaratory relief sought by potential infringers. In *Farmaceutisk*, the plaintiff, Farmaceutisk, sued for infringement, and the defendant, Solvay, counterclaimed seeking a declaratory judgment that Farmaceutisk's patent¹¹⁰ was invalid, and that Solvay's competing product did not infringe this patent.¹¹¹ The court dismissed Farmaceutisk's infringement suit, but agreed to hear Solvay's counterclaim.¹¹² Solvay was in the process of conducting clinical trials for its tablets containing 5-ASA, and was supplying the drugs to physicians to collect information for submission to the FDA.¹¹³ Solvay had not yet filed a New Drug Application with the FDA, but stated that it intended to do so within the year, and further contended that it would not change the formulation of its product during the FDA approval process.¹¹⁴ Solvay presented these arguments to show that its actions represented the sufficient "preparation to produce" the product necessary to ensure that an actual controversy exists which would warrant a declaratory judgment action.¹¹⁵ Farmaceutisk contended that Solvay's declaratory judgment

107. *Telectronics*, 982 F.2d at 1523; *Intermedics*, 775 F.2d at 1280.

108. *Beisler v. Commissioner*, 814 F.2d 1304, 1307 (9th Cir. 1987).

109. 25 U.S.P.Q.2d (BNA) 1344, 1346 (N.D. Ga. 1992).

110. *Id.* at 1346. The patent, U.S. Patent No. 4,496,553, described a method for treating ulcerative colitis by orally administering 5-aminosalicylic acid [hereinafter 5-ASA]. *Id.*

111. *Id.*

112. *Id.* at 1347.

113. *Id.* at 1346.

114. *Id.*

115. *Id.* at 1350.

action should be denied, since Solvay's actions were protected by section 271(e)(1), and thus it was not in an immediate position to infringe.¹¹⁶ The court acknowledged the need for Solvay to establish its rights prior to expending time and resources on the prosecution of an application with the FDA. The court stated,

Solvay, if at all possible, simply does not want to assume the financial risk of pending litigation years down the road after having expended significant additional resources on the project. Solvay would prefer to have what it considers the ripe issues of the patent's invalidity and its product's infringement resolved now.¹¹⁷

The court, however, declined to hear Solvay's declaratory judgment action on the issue of infringement.¹¹⁸ The court found that the issue of infringement was too remote, because Solvay was clearly within the provisions of section 271(e)(1), and therefore not infringing *Farmaceutisk's* patent.¹¹⁹

The court in *Farmaceutisk* did agree to hear Solvay's declaratory judgment action on the issue of the validity of *Farmaceutisk's* patent.¹²⁰ The court explained its policy reasons for this decision:

[P]ermitting new drug manufacturers, at their choosing and subject to court discretion, to test the validity of a patent-in-issue early on in the development process best serves the competing interests of protecting valid patents, protecting new drug manufacturers during the testing process, and moving alternative drugs into the market.¹²¹

While this is a step in the right direction, it would be far preferable for parties to be able to establish their rights on both the issue of patent validity and infringement at the same time, thus avoiding further litigation. Many companies, like Solvay or Zenith,¹²² wish to clear the infringement hurdle at the same time they clear the FDA hurdle. Such companies may be reluctant to invest the resources necessary to successfully prosecute an application before the FDA if they are unsure whether their product infringes a patented product. The interpretation of section 271(e)(1) used by the court in *Farmaceutisk* prevents companies from obtaining the early adjudication of rights needed by such companies to determine whether they should continue to invest in the development of their new products.

116. *Id.*

117. *Id.*

118. *Id.* at 1351.

119. *Id.* at 1351-52. The court added that it was not "legally clear when Solvay will leave the safe harbor and be subject to an infringement action." *Id.* at 1352.

120. *Id.* at 1351 ("Unlike the alleged infringing product, the patent is a fixed target which will not change and is only subject to a judicial determination as to its scope and validity.").

121. *Id.* at 1353.

122. *See supra* notes 79-84 and accompanying text.

V. CONCLUSION

Although courts are justified in abstaining from granting declaratory relief where no actual controversy exists, the courts should not automatically find that no actual controversy exists whenever one party is seeking FDA approval. The finding that one party is within section 271(e)(1) should not be automatic; it should depend upon the circumstances of the case.

In the passing of the PTR Act, Congress intended to do "what the Congress has traditionally done in the area of intellectual property law; balance the need to stimulate innovation against the goal of furthering the public interest."¹²³ The PTR Act was written to achieve the dual purposes of increasing incentives for research and providing competing products to the market more quickly. The courts' interpretation of section 271(e)(1), however, is contrary to these goals.

Section 271(e)(1) was never intended to shelter companies who have no intention of waiting until the expiration of the relevant patent to release their infringing products into the market. To allow such activity weakens patent rights and decreases the incentive to engage in expensive research and development. This is clearly contrary to the reasons given by Congress for the passing of section 201 of the PTR Act,¹²⁴ which provides for the extension of patent terms.¹²⁵ The court's interpretation of section 271(e)(1) is also contrary to explicit language in the legislative history of section 271(e)(1), which clearly states that the exemption is intended to allow competing products to enter the marketplace as soon as possible after the expiration of the pioneer patents.¹²⁶

Nor was section 271(e)(1) intended to prevent companies from obtaining an early adjudication of their rights while they are engaged in seeking FDA approval. This would also serve to deter companies from investing in the development of new drugs and medical devices.

In addition, the holdings of the courts in these recent cases are

123. H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. 2, at 30 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2714.

124. Codified as amended at 35 U.S.C. § 156 (1984).

125. H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. 2, at 6 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2690. "[P]roponents of [patent term restoration] have argued that without some form of legislative relief in this area there would be a diminished stimulus to innovation and research. Thus, it is argued patent term extensions will create incentives for increased expenditures." *Id.*

126. H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. 1, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

inconsistent with the purpose of the remedy of declaratory judgments.¹²⁷ There is a strong need in intellectual property cases for early adjudication of rights because damages can quickly become staggering. These damages are passed on to consumers and eliminate resources which could be used to develop new technologies. Thus, the courts' denial of declaratory actions when one party is under the exemption of section 271(e)(1) ultimately harms society. This is clearly contrary to the purpose of the United States Patent system.

The courts are determined to expand section 271(e)(1) from the original, limited compromise between generic and pioneer pharmaceutical manufacturers, to a broad experimental use exception. Nowhere in the legislative history of the PTR Act was such a broad exception envisioned. A broad experimental use exception weakens patents and deters investment in research and development.

Congress clearly defined its objectives in passing the PTR Act: to make low cost generic drugs available to the public as quickly as possible, and to encourage expenditures on the development of new drugs. By interpreting section 271(e)(1) as requiring the denial of all declaratory judgment suits when one party is engaged in FDA trials, the courts are preventing these objectives from being met. If the courts do not reevaluate their interpretation of the PTR Act, this legislation could result in harming both the U.S. Patent System and the American public.

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127. *Lukenbach S.S. Co. v. United States*, 312 F.2d 545, 548 (2d Cir. 1963). "The purpose of the declaratory remedy is to 'avoid accrual of avoidable damages to one not certain of his rights and to afford him an early adjudication without waiting until his adversary should see fit to begin suit, after damage had accrued.'" *Id.* (citing and quoting *E. Edlmann & Co. v. Triple-A. Specialty Co.*, 88 F.2d 852 (7th Cir. 1937)).